

## **REMARKS**

This amendment and these remarks are responsive to the final Office action dated December 8, 2006.

### **Claims:**

In the Office action, claims 54-73 were pending. Claims 54-68 were rejected and claims 69-73 were withdrawn as being directed to a non-elected invention. Applicants affirm the Examiner's election of the claims identified as Invention I. however, applicants traverse the Examiner's restriction for the reasons set forth below.

### **Reasons for traversal:**

Applicants respectfully submit that there is no serious burden placed on the Examiner to examine the claims identified as elected Invention II. The Office action states that the apparatus described by the claims identified as Invention I can be used to practice another and materially different process from the process of the claims identified as non-elected Invention II. The Office action specifically states that the apparatus can be used without detecting a pre-complexing fluorescent signature and a post-complexing fluorescent signature. However, currently pending claim 58 recites, "The device of claim 54 wherein the first and second fluorescent tags initially have an identified pre-complexing fluorescent signature; and, upon binding between the first or second biomolecule and an analyte, the first or second fluorescent tag associated with the analyte-bound biomolecule has a detectable post-complexing fluorescent signature." Accordingly, because the Examiner has already examined claim 58, applicants respectfully submit that no serious burden is placed on the Examiner because the Examiner has already searched for prior art and examined the limitation that, as stated by the Office action, defines Invention II.

Rejections under 35 USC §112:

Claims 54-68 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. As suggested by the Examiner, the applicant has amended claims 54 and 63 to recite "...a first *type of* biomolecule..." and "...a first *type of* fluorescent tag..." as well as "...a second *type of* biomolecule..." and "...a second *type of* fluorescent tag..." Such amendment is made simply to clarify what is intended by the applicant in the current claims. No new matter is added by way of these amendments. Accordingly, applicants believe the Examiner's rejection of claim 54-68 under 35 U.S.C. §112, second paragraph are mooted by applicants' amendments.

Rejections under 35 USC §103:

Claims 54-57 and 62-67 are rejected under 35 USC §103 as being unpatentable over Myers, 6,267,884 in view of Efimov 7,115,738 and further in view of Chandler *et al.* 6,268,222. The Office action states that Myers teaches the invention substantially as claimed except that Myers fails to teach the use of different tags on different biomolecules. The Office action states that Efimov teaches the use of capture probes on beads for separation and that after separation, separated molecules can be detected or analyzed. The Office action further states that Efimov teaches detectable labels including fluorescent labels, but fails to teach different labels on different beads. The Office then states that Chandler teaches the use of different fluorescent dyes on different particles, but fails to teach that the dye is coupled to the biomolecule. Applicants respectfully traverse the rejection for at least the following reasons:

First, Myers and Efimov are not prior art to the presently claimed invention. As evidenced by the attached Declaration under §1.131, applicants conceived of their invention

before the effective prior art dates of the Myers and Efimov disclosures.

The present application claims the benefit of U.S. Provisional Patent Application No. 60/246,564 (“the ‘564 application”) filed November 8, 2000. The ‘564 application clearly supports the currently pending claims. See, for example, page 20 of the ‘564 application which depicts microaffinity columns with receptor-bearing beads. The beads are packed into different sections with the populations of beads in each section being attached to different types of biomolecules. See also the 25 page section entitled “FRET Based detection of Analyte in Microfluidic Channels Using Flow Cytometry-Calibrated Molecular Assemblies on Beads” as well as the rest of the application. Accordingly, applicants respectfully submit that the current application is entitled to claim the benefit of the filing date of November 8, 2000, the filing date of the ‘564 application.

MPEP § 715 states Affidavits or declarations under 37 CFR 1.131 may be used, for example...to antedate a reference or activity that qualifies as prior art under 35 U.S.C. 102(a) and not under 35 U.S.C. 102(b), e.g., where the prior art date under 35 U.S.C. 102(a) of the patent, the publication or activity used to reject the claim(s) is less than 1 year prior to applicant’s or patent owner’s effective filing date. Myers was filed January 4, 2000, less than one year prior to the effective filing date of the present application. Efimov was filed March 13, 2001, after the effective filing date of the present application, but claims the benefit of two provisional applications, provisional application serial no. 60/250,334, filed Nov. 30, 2000 and 60/189,190, (“the ‘190 application) filed Mar. 14, 2000. Only the ‘190 application was filed prior to the effective filing date of the present application. However, it was also filed less than one year prior to the effective filing date of the present application.

Additionally, as indicated in the attached declaration, applicants conceived of the

presently claimed invention prior to January 4, 2000 and at least as early as June 1999. Furthermore, applicants continued to work diligently towards perfecting the invention until at least November 8, 2000, the filing date of the '564 application, as evidenced by continued experiments, presentations, publications, and the like. Applicants therefore conceived of the invention prior to the filing of the '884 and the '190 application. Therefore, applicants are able to swear back of both the Myers and Efimov references, invalidating them as prior art references.

Accordingly, Myers and Efimov are not prior art to the presently claimed invention and, as implicitly and explicitly stated in the Office action, Chandler fails to teach the limitations that the Examiner indicated were taught by Myers and Efimov. Accordingly, applicants respectfully request that the rejection of claims 54-57 and 62-67 be removed.

Second, even if applicants were unable to swear back of Myers and Efimov and are only entitled to the benefit of the filing date of the '564 provisional application, applicants respectfully submit that Efimov is not prior art to the presently claimed invention. As stated above, the Efimov patent was filed on March 13, 2001, which is after November 8, 2000, the filing date of the '564 application and the effective filing date of the current application. Only the '190 provisional application was filed prior to the effective filing date of the current application. However, in order for the March 14, 2000 filing date to be effective as the prior art date of Efimov, the disclosure relied upon by the Examiner in the Efimov patent must properly support the subject matter relied upon to make the rejection in compliance with 35 U.S.C. §112.

As stated above, Efimov is relied upon to teach the use of capture probes on beads for separation and that after separation, separated molecules can be detected or analyzed. However, the '190 provisional application does not make any mention of the attachment of capture probes on beads for separation, nor does the '190 application teach different probes on different

populations of beads. In fact, the only beads discussed in the '190 provisional application are magnetic beads which are used as a labeling method for detection of post complexed PNA:DNA molecules. Efimov is further relied upon to teach fluorescent labels. However, there is no mention in the '190 provisional application of fluorescent labels. The only labels discussed are the aforementioned magnetic beads and p32. Accordingly, the '190 provisional application fails to teach or provide support for any of the subject matter for which the Efimov patent is recited in the rejection.

Furthermore, even if the '190 application did make mention of any of the limitations for which the Efimov reference is relied, applicants submit that Efimov fails to enable those limitations. The '190 provisional application includes a number of research proposals which outline the types of experiments they would like to perform, the desired results or goals of the proposed experiments, and the possible pitfalls. Throughout the '190 application, the applicants repeatedly emphasize that it will be necessary to conduct experiments to determine correct protocols and conditions in order to determine whether or not any of the proposed results can be achieved. They also discuss past failures for similar projects and the possibility of failure of the present experiments. Accordingly, applicants submit that the '190 application fails to enable the experiments that are described.

Accordingly, because the '190 application fails to enable or provide support for the teachings upon which the Efimov reference is relied, applicants respectfully submit that the Efimov reference is not entitled to the March 14, 2000 filing date as a prior art reference and, therefore, for the purposes of the present rejections, Efimov is not prior art to the current application.

Because Efimov is not prior art to the current application, and because alone, or in

combination, the Myers and Chandler references fail to teach or make obvious all of the limitations of the current claims, applicants respectfully request that the rejection of claims 54-57 and 62-67 be removed.

Third, even if Myers and Efimov were prior art to the present application, the Examiner has not established a prima facie case of obviousness. In order to establish a prima facie case of obviousness, the examiner must show that the cited references teach or make obvious each and every limitation in the rejected claims, there must be motivation to combine the references, and there must be a reasonable expectation of success.

There is no motivation to combine the teachings of the cited references, nor would there be any expectation of success without undue experimentation. The '190 provisional application discusses, at length, solubility issues associated with PNAs and repeatedly states that while it is possible that the PNAs created by Dr. Efimov may resolve some of these issues, numerous experiments need to be performed to determine the proper conditions under which the Efimov PNAs are effective for use in separation assays. As such, there is no reason to believe that without undue experimentation, someone skilled in the art would be able to construct a column with the capture probes described in the '190 provisional application attached to beads. Accordingly, there would be no motivation to combine the teachings of the '190 provisional application with the teachings of Myers and Chandler in order to produce the presently claimed invention. Moreover, even if such motivation existed, there would be no reasonable expectation of success absent undue experimentation.

Accordingly, for at least the reasons described above, applicants respectfully request that the rejection of claim 54-57 and 62-67 be removed.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers, Efimov,

and Chandler in view of Hopp et al., 4,851,341. The rejection is traversed. Hopp is recited to show the teaching of the FLAG sequence. Without commenting on whether or not applicants agree with the Examiner's characterization of Hopp, because Hopp does not cure the failings described above with respect to the rejections of claim 54-57 and 62-67, applicants respectfully request that the rejection of claim 61 be removed for at least the reasons identified above.

Claims 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers, Efimov, and Chandler in view of Craig *et al.* 6,972,198. The rejection is traversed. Craig is recited to teach the detection of pre-complexing and post-complexing fluorescent signatures. Without commenting on whether or not applicants agree with the Examiner's characterization of Craig, because Craig does not cure the failings described above with respect to the rejections of claim 54-57 and 62-67, applicants respectfully request that the rejection of claims 58-60 be removed for at least the reasons identified above.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers, Efimov, and Chandler in view of Yon-Hin et al., 6,440,645. The rejection is traversed. Yon-Hin is recited to teach multiple entry ports for analyte delivery. Without commenting on whether or not applicants agree with the Examiner's characterization of Yon-Hin, because Yon-Hin does not cure the failings described above with respect to the rejections of claim 54-57 and 62-67, applicants respectfully request that the rejection of claim 63 be removed for at least the reasons identified above.

Conclusion:

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions,

or if a telephone interview would in any way advance prosecution of the application, the Examiner is requested to please contact the undersigned attorney of record.

Respectfully submitted,

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